Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

comparison of low level laser acustimulation and no intervention on gag reflex management on patients undergoing maxillary impression

Protocol summary

Study aim
effect of low level laser acustimulation on gag reflex

Design
this parallel group single blind phase 2-3 randomised trialwas performed on 30 - allocated by site to case and control groups - .

Settings and conduct
30 patients were enrolled from Mashhad Dental School . before impression gag reflex severity was measured by GPI (GAG PREVENTION INDEX) including : 1- tolerance of alginate tray until complete setting 2- tolerance of alginate tray just in initial placement 3- tolerance of empty tray 4- intolerance of tray in oral cavity to asses subjective gag reflex severity VAS(Visual Analog Scale) was used . in a ruler numbering 0 to 10 . zero representing no gag reflex and 10 representing the worst gag reflex even experienced. number of vomiting cycles also was registered . in intervention group low level laser (Ga-Al-As) 810nm was irradiated foe 1 minute to cv 24 and P6 acupuncture points . after irradiation impression was achieved in 3 mins and severity of gag reflex was registered .in control group all steps were similar except that laser was switched off.this was performed to assess placebo effect.

Participants/Inclusion and exclusion criteria
patients admitted to Mashhad Dental school needing alginate impression for prostodontic or orthodontic treatment ,20 to 60 years old suffering from severe gag reflex

Intervention groups
in intervention group GaAlAs 810 nm,200Mw low level laser was apllied on P6,Cv24 acupuncture points for 1 minute. the skinn was dis infected by alcohol and the laser prob was applied on 1 cm distance from skin . in control group all situation was similar except that laser was switched off.

Main outcome variables
gag reflex severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080906001216N4**
Registration date: **2020-11-29, 1399/09/09**
Registration timing: **retrospective**

Last update: **2020-11-29, 1399/09/09**
Update count: **0**

Registration date
2020-11-29, 1399/09/09

Registrant information

Name
Pegah Mosannen Mozaffari

Name of organization / entity
research center of Mashhad dental faculty,Mashhad University of medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-23, 1396/07/01

Expected recruitment end date
2018-02-20, 1396/12/01

Actual recruitment start date
2017-09-23, 1396/07/01

Actual recruitment end date
2018-05-22, 1397/03/01

Trial completion date
2018-06-22, 1397/04/01

Scientific title
comparison of low level laser acustimulation and no intervention on gag reflex management on patients undergoing maxillary impression

Public title
effect of low level laser acustimulation on gag reflex management

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
patient admitted to Mashhad Dental School suffering severe Gag reflex need Alginate impression for denture fabrication or orthodontic treatment
Exclusion criteria:
disagreement to participate in trial

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
allocation to two groups by ttp://www.randomizer.org (two groups A and B

Blinding (investigator's opinion)
Single blinded

Blinding description
patient was blind about sham laser

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences-Research Ethics Committee
Street address
Vakil Abad BLV
City
Mashhad
Province
Razavi Khorasan
Postal code
911735984
Approval date
2018-09-12, 1397/06/21
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1397.047

Health conditions studied

1

Description of health condition studied
gag reflex
ICD-10 code
R11
ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
gag reflex management
Timepoint
just after intervantion
Method of measurement
GPI = gag prevention index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: in this group low level laser acustimulation on accumuncture points for controlling gag reflex (cv24 ,pc6) was performed before obtaining maxillary impression
Category
Prevention

2

Description
Control group: in this group sham laser (placebo)was placed on accumuncture points for controlling gag reflex (cv24 ,pc6) before obtaining maxillary impression.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Dental School
Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Pegah Mosannen Mozafari
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

data including demographic data signs and symptoms and intervention results will be released

When the data will become available and for how long

2 months after article publication

To whom data/document is available

academic staff

Under which criteria data/document could be used

the data can be used in further studies with citation to main article

From where data/document is obtainable

pegah mosannen mozafari

What processes are involved for a request to access data/document

email communication , the data will be sent in 4 weeks

Comments